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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,421	12/05/2003	Venkatakrishna Shyamala	PP-20030.003	8395

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EXAMINER
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SALVOZA, M FRANCO G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,421	<b>Applicant(s)</b> SHYAMALA, VENKATAKRISHNA	
	<b>Examiner</b> M. Franco Salvoza	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to an isolated and radiolabeled oligonucleotide, classified in class 536, subclass 22.1.
- II. Claims 12-29, drawn to a method for detecting the presence of West Nile virus, classified in class 436, subclass 501.
- III. Claims 30-36, drawn to a kit for detecting the presence of West Nile virus in a biological sample, classified in class 436, subclass 501.
- IV. Claims 37, drawn to a pair of amplification primers for detecting West Nile virus, classified in class 536, subclass 22.1.
- V. Claims 38-39, drawn to a set of oligonucleotides for specifically capturing WNV nucleic acid, classified in class 536, subclass 22.1.
- VI. Claim 40, drawn to a method of preparing a blood supply free from West Nile virus, classified in class 435, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case an isolated oligonucleotide can be used as a probe or to code for

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complementary nucleotide sequences or amino acids. A wide range of diagnostics and probes and biological agents other than nucleotides such as antibodies can be used to detect viruses such as West Nile.

Inventions I and III are materially different products. The oligonucleotide can be used to code for amino acids or complementary nucleic acid strands, while a kit can detect the presence of West Nile viruses using a wide range of products other than nucleotides such as epitope-specific antibodies.

Inventions I and IV are materially different products. A pair of primers can be used to begin a complementary sequence of nucleic acids, while an oligonucleotide can be used as a probe or to code for a particular amino acid.

Inventions I and V are materially different products. A set of oligonucleotides like the one mentioned can be used to capture a specific nucleic acid, while a particular oligonucleotide can be used to code for a particular set of polypeptides.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are used for different purposes. An oligonucleotide can be used on a nucleic acid level as a probe, while a method of preparing a West Nile viruses-free sample of blood has a different administrative purpose.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the West Nile virus can be detected by plaque assay or reverse transcriptase PCR, while a kit consisting of oligonucleotides can be used to detect other viruses other than West Nile.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the West Nile virus can also be detected by assay or antibody, while the pair of amplification primers can also be used to amplify nucleic acid strands.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a set of oligonucleotides can be used as a set of primers to amplify DNA, while a method for detecting the presence of West Nile virus can use materially different products such as plaque assays and antibody screens.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case a method of detecting a virus is materially different from a method of preparing a virus-free sample of blood.

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Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, a kit for detecting the presence of West Nile can use materially different products such as antibodies, while the subcombination has separate utility such as a way to start complementary nucleic acid synthesis.

Inventions III and V are materially different products. A kit for detecting the presence of West Nile has a different function than a set of oligonucleotides, which can be used as a probe or nucleic acid strand primer.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different purposes, one to diagnose, and the other to provide virus-free blood.

Inventions IV and V are different products. A pair of primers can be used in PCR to amplify DNA strands, while a set of oligonucleotides can be used as probes to hybridize to complementary oligonucleotides.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions – one to provide a blood supply free from virus, while a pair of amplification primers is used as a complementary probe or to synthesize DNA.

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Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and effects – one to probe specific nucleic acids, while the other is used to provide virus-free product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper.

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**Election of Invention Group I**

If group I is chosen, election of one of the following species is required for claims 1-11:

- SEQ ID: 1
- SEQ ID: 2
- SEQ ID: 3
- SEQ ID: 4
- SEQ ID: 5
- SEQ ID: 6
- SEQ ID: 7
- SEQ ID: 8

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- SEQ ID: 9
- SEQ ID: 10
- SEQ ID: 11
- SEQ ID: 12
- SEQ ID: 13
- SEQ ID: 14
- SEQ ID: 15
- SEQ ID: 16
- SEQ ID: 34
- SEQ ID: 35
- SEQ ID: 37
- SEQ ID: 42
- SEQ ID: 43
- SEQ ID: 45
- SEQ ID: 46
- SEQ ID: 50
- SEQ ID: 52
- SEQ ID: 53
- SEQ ID: 54
- SEQ ID: 55

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus



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deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 et seq. (MPEP § 803.04).

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**Election of Invention Group II**

If Group II is chosen, election of one of the following sense primer species is required for claim 12(a):

- SEQ ID NO: 34 or a nucleotide having at least 90% sequence identity thereto
- SEQ ID NO: 37 or a nucleotide having at least 90% sequence identity thereto
- SEQ ID NO: 42 or a nucleotide having at least 90% sequence identity thereto

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 et seq. (MPEP § 803.04).

If Group II is chosen, election of one of the following antisense species is required for claim 12(b):

- SEQ ID NO: 35 or a nucleotide having at least 90% sequence identity thereto
- SEQ ID NO: 38 or a nucleotide having at least 90% sequence identity thereto
- SEQ ID NO: 43 or a nucleotide having at least 90% sequence identity thereto

If Group II is chosen, election of one of the following species is also required for claim

17:

- SEQ ID: 1
- SEQ ID: 2
- SEQ ID: 3
- SEQ ID: 4
- SEQ ID: 5
- SEQ ID: 6
- SEQ ID: 7
- SEQ ID: 8
- SEQ ID: 9
- SEQ ID: 10
- SEQ ID: 11
- SEQ ID: 12
- SEQ ID: 13
- SEQ ID: 14
- SEQ ID: 15
- SEQ ID: 16
- SEQ ID: 45
- SEQ ID: 46
- SEQ ID: 50

If Group II is chosen, election of one of the following species is required for claim 22:

- the sequence of SEQ ID NO:52 or the sequence of SEQ ID NO:53 when the sense primer comprises the sequence of SEQ ID NO:34

- the sequence of SEQ ID NO:54 when the sense primer comprises the sequence of SEQ ID NO:37

- the sequence of SEQ ID NO:55 when the sense primer comprises the sequence of SEQ ID NO:42.

If Group II is chosen, election of one of the following species is required for claim 29:

- SEQ ID: 40

- SEQ ID: 41

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**Election of Invention Group III**

If group III is chosen, election of one of the following species is required for claim 30:

- SEQ ID: 1

- SEQ ID: 2

- SEQ ID: 3

- SEQ ID: 4

- SEQ ID: 5

- SEQ ID: 6

- SEQ ID: 7

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- SEQ ID: 8
- SEQ ID: 9
- SEQ ID: 10
- SEQ ID: 11
- SEQ ID: 12
- SEQ ID: 13
- SEQ ID: 14
- SEQ ID: 15
- SEQ ID: 16
- SEQ ID: 45
- SEQ ID: 46
- SEQ ID: 50

and one of the pairs of:

- SEQ ID NOS: 34 and 35
- SEQ ID NOS: 37 and 38
- SEQ ID NOS: 42 and 43

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 et seq. (MPEP § 803.04).

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**Election of Invention Group IV**

If group IV is chosen, election of one of the following species is required for claim 32:

- the sequence of SEQ ID NO:52 or the sequence of SEQ ID NO:53 when the primer oligonucleotides comprise at least 10 contiguous nucleotides from SEQ ID NO:34 and SEQ ID NO:35

- the sequence of SEQ ID NO:54 when the primer oligonucleotides comprise at least 10 contiguous nucleotides from SEQ ID NO:37 and SEQ ID NO:38

- the sequence of SEQ ID NO:55 when the primer oligonucleotides comprise at least 10 contiguous nucleotides from SEQ ID NO:42 and SEQ ID NO:43

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 et seq. (MPEP § 803.04).

If group IV is chosen, election of one of the following species is required for claim 37:

- SEQ ID: 34/ SEQ ID: 35

- SEQ ID: 37/ SEQ ID: 38

- SEQ ID: 42/ SEQ ID: 43

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one species is not required for the other species, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410.

The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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